Response to USEPA Comments to Data Usability and Data Evaluation Plan, received 04/01/10

Cmt No.	Section	Comment	CPG Response
General Comments			
1	General comment	EPA has reviewed the draft Data Usability and Data Evaluation Plan for the Lower Passaic River Study Area Risk Assessments submitted on February 26, 2010. Overall, we have some significant concerns with the document, not the least of which is how it fits into the larger questions of how the risk assessments will be conducted. As such, we will not approve this document, nor consider it final, until all (or at least more) of the risk assessment-related documents are submitted and reviewed holistically. We anticipate that a series of conversations and written exchanges on this topic will take place over the coming weeks and, most likely, months. The draft Data Usability Plan provides a good starting point for this dialogue. Our major concerns with this specific document are as follows:	Comment noted.
2	General comment-bullet 1	A date of ten years before the 2007 CPG Settlement Agreement was selected as the cutoff to establish the age of historical data that will be considered for use in the risk assessments. This date does not have a scientific basis and automatically excludes older data that should at least be considered for use in the assessments. As the document suggests, trend analyses need to be conducted; these analyses should be conducted prior to determining which data should or should not be used.	Per the December 14 and December 16, 2010 meetings, EPCs in the risk assessments will be calculated using current (CPG) data only and a discussion of older data and trends in concentrations will be included in the RAs and RI. The text has been revised accordingly.
3	General comment-bullet 2	The document also states that all data collected by the CPG as part of EPA-approved QAPPs and/or QAPP addenda automatically meets all Data Quality Objectives for the risk assessments. While most of the CPG data should indeed meet DQOs, all data must still be vetted against those DQOs prior to use.	All CPG data will be reviewed for consistency with DQOs.
4	General comment-bullet 3	The document does not include a reference to the Risk Assessment Guidance for Superfund (RAGS), Part D, and the associated data usability worksheets. RAGS Part D must be used as part of the process, to evaluate data for the risk assessment.	The CPG has added reference to RAGS Part D, and will incorporate a similar format to the data usability worksheets as part of the process to evaluate data for the risk assessment. Consistent language has been added to Section 3.
5	General comment-bullet 4	EPA is working on a comprehensive review of the PREmis database, and will be addressing the concerns raised by the CPG. At this point, data should not be excluded simply because it is not entered properly or consistently in the database.	The text has been revised to acknowledge that USEPA is working on a revision to the PREmis database.
6	General comment	More specific comments follow, and we reserve the right to send additional comments as our discussions on these topics progress.	Comment noted.

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Specific Comments			
1	Section 1	The document states the "evaluation of data usability for other aspects of the LPRSA RI/FS (e.g., site characterization, remedial studies, trend analysis of chemical concentrations over time, and modeling) and regional background data that will be used to support the risk assessments are not addressed in this plan." Please indicate when and in which documents data usability will be evaluated for other RI/FS uses.	The data rules and DQOs for other aspects of the RI/FS will be provided in future addenda to this document, as needed per discussion between CPG and USEPA.
2a	Section 2.1.2	a. EPA agrees that the data loaded on PREmis needs to be evaluated, and we are actively developing a solution for moving forward. However, note that the majority of the historical data were collected under USEPA quality assurance/quality control (QA/QC) procedures, using approved QAPPs. Appropriate QA/QC procedures appear to have been used to generate most existing datasets, and the data have been used to support other risk assessments. Note that reports, and the associated metadata information, are available via hardcopy for 7 of the 13 sediment datasets and 3 of the 6 biological tissue datasets for use in the risk assessments.	Comment noted.
2b	Section 2.1.2	b. The acceptability of datasets (whether historical or collected by CPG) for use in risk assessments should be evaluated using the DQOs, even as database maintenance continues. The format of existing data should not impact data usability, especially since the EPA Region 2 MEDD format was not required for use on this project until 2007.	Agree that all current data will be reviewed for consistency with DQOs for use in the risk assessments. The text has been revised to acknowledge that USEPA is working on a revision to the PREmis database and the text regarding the Region 2 MEDD format has been deleted.
3	Section 2.2	The second paragraph of this section states that CPG-collected data "are assumed to meet DQOs specified for the baseline risk assessments." Change "are assumed to" to "will be evaluated as to whether they."	The CPG has revised the Data Usability and Data Evaluation Plan to state that CPG-collected data will be evaluated as to whether they meet DQOs specified for the baseline risk assessments.
4a	Section 2.2.1	a. The "Event Level" DQOs listed are overly restrictive and would likely eliminate many recent datasets that may be useful without a scientifically valid reason.	Event Level DQO No, 2 has been deleted; however, strict risk assessment DQOs are needed to ensure that EPCs are based on accurate and representative data. The event level DQOs ensure that the data are accurate (i.e., data reports are available for review), and relevant (i.e., data represent current exposure conditions). Please note that these risk assessment-specific DQOs do not restrict data for use in other aspects of the RI/FS (e.g., trend analysis, site characterization, background).

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4b	Section 2.2.1	b. Other data types (toxicity, bioassay, and physical data) are listed in the document, but criteria for these data types are not identified.	The text has been revised to state that the DQOs provided in this document apply to all data that will be used to derive exposure estimates in the risk assessments (i.e., chemistry, toxicity, and community data). DQOs outlined in this document, unless otherwise specified, apply to all of these data types.
4c	Section 2.2.1	c. The potential for inclusion of sediment samples from deeper than 0-6 inches should be evaluated as part of the risk assessment planning process. A more detailed discussion of the sediment sample selection process needs to be presented in either this or one of the upcoming documents (see also Section 2.2.3).	Per the December 14, 2010 meeting, the evaluation of surface sediment defined as the depth from 0 to 6 in. will be used in the risk assessments for EPC calculations.
4d	Section 2.2.1	d. In the third bullet of this section, it is not clear why only data that have been processed in a "manner consistent with the Benthic QAPP" would meet the requirements of this DQO. Why is this stipulation not also extended to surficial sediment and surface water as well? If the issue is integration, it would be better to consider appropriate approaches rather than to disregard other data sets.	Event Level DQO No, 2 has been deleted.
4e	Section 2.2.1	e. As is noted in the general comments, the timing of the 2007 CPG Settlement Agreement is not relevant to the risk assessment. If the CPG wishes to evaluate data collected in the last 10 years, then they should propose to examine data from 2000 to 2010; however, it is preferred that they do not exclude the Tierra Solutions, Inc. 1995 RI Study (which is close to the proposed cut-off date of 1997). The 1995 sampling program is the only other comprehensive set of sediment data available, albeit for only part of the river under investigation, and provided analytical data for locations not otherwise sampled. In addition, the risk assessments will need to evaluate both current and future conditions for receptors. Even if trend analyses suggest that conditions have changed within the LPRSA since the time that these samples were collected, the 1995 data along with subsurface analytical results (collected under various programs) may be the best way to estimate potential exposures.	Per the December 14 and December 16, 2010 meetings, EPCs in the risk assessments will be calculated using current (CPG) data only and a discussion of older data and trends in concentrations will be included in the RAs and RI. The text has been revised, accordingly.

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5	Section 2.2.2	DQO No. 1: As stated, sediment samples collected prior to dredging or capping no longer reflect current conditions. However, data from these areas may still be useful as part of the risk assessment process, for example during trend analyses.	CPG agrees that these data may be useful for RI tasks, such as trend analyses. The CPG does not agree that sediments collected prior to dredged or capped data are appropriate for use in the risk calculations in current or future conditions. Per the December 14 and December 16, 2010 meetings, EPCs in the risk assessments will be calculated using current (CPG) data only.
6	Section 2.2	DQO No. 2: The statement "only data collected from within the LPRSA will be used to calculate risk estimates" suggests that data collected above Dundee Dam or on the tributaries will be eliminated from the risk assessment. Please clarify this statement.	Paragraph 14 subparagraph l of the May 2007 RI/FS Settlement Agreement defines the LPRSA as: "the 17-mile stretch of the Lower Passaic River and its tributaries from Dundee Dam to Newark Bay". Per the December 14, 2010 meeting, the Study Area for the BERA will be defined as the LPR from RM 0 to RM 17.4 of the main stem and to the head of tide for the tributaries.
7	Section 2.2.4	DQO No. 1: Historical data may be marked with either a U- or an ND-qualifier, and they are generally used interchangeably. For these non-detected concentrations, the laboratory may report either the method detection limit, the reporting limit, or the laboratory quantitation limit, depending on their scope of work. These details may be obtainable from the labs, even if they are not currently entered in the database.	Text has been revised to state that non-detects may be identified by a U- or ND- qualifier and that if no RL is reported, an effort will be made to contact the laboratory for an RL.
8a	Section 2.2.4	DQO No. 2: a. In some instances individual component results may not be available. The totals results may have been reported directly from the laboratory and individual components may not have been captured in PREmis or reported from the laboratory. This should not necessarily preclude the use of these results from the risk assessment.	The CPG disagrees that data based on sums without component results may be usable and are appropriate for use in the risk assessments and the RI. CPG believes the component results are necessary for the calculation of EPCs because consistent data rules (i.e., summing rules) must be applied to the dataset for the calculation of EPCs. Per the December 14, 2010 meeting, historical sums where the individual component result is not available will be used only in general trend analysis, and the uncertainty of using these sums will be discussed. These data will not be used in EPC calculations.
8b	Section 2.2.4	DQO No. 2: b. Include a cross reference to Table 3 and Section 3.1.	A reference to Section 4.1 (previously Section 3.1) is included in the DQO text.

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9a	Section 2.2.4	DQO No. 3: a. Delete the phrase "publicly available" from the discussion of SOPs. Data should not necessarily be eliminated because a laboratory considers their SOPs to be confidential documents. Prior experience shows that business confidential SOPs can be obtained for review and approval by both EPA and the CPG.	The CPG agrees that data may be used if the SOPs for these proprietary methods can provided to the CPG and USEPA for review; otherwise, the CPG maintains that the data should be eliminated from use in the LPRSA RI/FS and will modify the plan as such. The language "publicly available" has been deleted.
9b	Section 2.2.4	DQO No. 3: b. The document states that inclusion of data obtained using low-resolution analysis methods will be made on a case-by-case basis. The determination process for vetting these data should be detailed in this document or elsewhere, for discussion and approval by EPA.	Comment noted. Text has been added stating that such data would be used on a case-by-case basis and per discussion with USEPA.
10	Section 2.2.4	DQO No. 5: "Invertebrate community data must be reported to the lowest practical taxonomic level." Lowest practical taxonomic level is clearly preferred, but even higher taxonomic levels can be useful if qualified appropriately and used carefully.	Agree and text states that the lowest practical taxonomical level is preferred, but higher taxonomical levels could still be used. It should be noted that the lowest practical taxonomic level represents the entire range of taxonomic classifications – it was not meant to refer to species, genus or even family level classification.
11	Section 2.2.5	The validation criteria are overly strict for data collected by other parties and will likely eliminate several historical datasets. For example, non-chemical parameters may not typically be validated. Historical biological data (*e.g.*, toxicity test and community surveys) were likely verified, not validated. These historical data should not necessarily be eliminated if they were generated in compliance with their planning documents.	The text has been revised to state that data for non-chemical parameters may be used even if no validation was completed on the dataset provided the data can be verified to meet USEPA acceptability criteria. However, in order to be comparable to the data collected under the approved LPRSA QAPPs, the validation of chemical data must be conducted as provided in the Data Usability and Data Evaluation Plan.
12	Section 2.2.5	DQO No. 3: This statement is generally true; however there may be documentation beyond the availability of Form 1s that define the quality checks used for a particular data set in PREmis. These quality assurance trails also speak to the overall quality of a particular dataset.	Language has been revised to state that if Form1s are not available, some other laboratory-generated documentation must be available to conduct a QC.
13	Section 2.2.6	As was noted earlier, the final list of DQOs should apply to all data, not just that collected by parties other than the CPG.	The Data Usability and Data Evaluation Plan was revised accordingly, per comment.

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14	Section 3.1	EPA is still evaluating how best to handle non-detects for congeners with multiple congeners, and Region 2 has contacted Headquarters for further guidance. As such, additional comments on this section will be made at a later date. In the meantime, however, it may be useful to select some examples from the existing dataset to determine the overall impact of using zero, one-half the detection limit, or the full detection limit on the calculated concentrations.	Comment noted. The text states that impact of using zero, one-half, or full detection limit values for summing on risk estimates will be evaluated.
15a	Table 3-1	a. The rationale for inclusion of an alkylated PAH (2-methylnaphthalene) in the PAH totals should be included.	2-methylnapthalene has been removed from the PAH sums.
15b	Table 3-1	b. More detail should be provided on the handling of DDD, DDE, and DDT in the summation since analysis and quantification of these compounds are frequently impacted by matrix interferences. It is likely that most of the Total DDx concentrations will be flagged in the risk assessment database.	PCBs present in the sample matrix are a known interference in the chlorinated pesticide analysis by GC/ECD (USEPA Method 8081A). However, the pesticide data that will be used in the risk assessment were determined using a high resolution technique (HRGC/HRMS, USEPA 1699 Mod) that does not have the same interference issues as the GC/ECD analysis, therefore this is not an issue for the current LPRSA dataset.
15c	Table 3-1	c. More detail should be provided on the handling of PCB co-elution.	The Data Usability and Data Evaluation Plan was revised accordingly, per comment; more detail on the reporting of PCB co-elutions results is provided in revised Table 4-1.
15d	Table 3-1	d. The evaluation of non-dioxin like PCBs should be conducted consistent with the examples provided in EPA's 1996 PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures, available at: http://cfpub.epa.gov/ncea/CFM/recorddisplay.cfm?deid=12486.	As stated in Section 3.4 of the Revised RARC Plan, the most current body of scientific information available at the time the baseline HHRA is conducted will be considered in the selection of appropriate dose-response values and approaches, including the evaluation of PCBs.
16a	Section 3.2	a. The handling of field duplicates is unclear. The introductory paragraph for the section states that one value will be used from the sample and duplicate pair. However, Section 3.2.2 states that both results will be used or averaged. These paragraphs should be consistent.	The discussion on field duplicates in Section 4.2 of the Data Usability and Data Evaluation Plan was clarified to say that a single result will be reported.
16b	Section 3.2	b. For the first bullet on Page 13, see Comment 10b. In addition, EPA PAH data generated by HRCG/LRMS are also valid and should take precedent over SVOC data.	Comment noted. Text has been revised to include USEPA method.

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16c	Section 3.2	c. If there are instances where samples were collected at the same location at different times, a third case should be included explaining how temporally variant samples would be used	CPG contends that data collected at different times should be treated as separate samples in the risk assessment database, therefore rules regarding the selection of a single result are not included in this section. Temporally collected samples may be combined in the development of EPCs, but will be stored as discrete samples in the risk assessment dataset.
16d	Section 3.2	d. The document states that "if a constituent is detected in only one duplicate, the detected value will be used." Such an instance should be accompanied by a rigorous QC review of the potential causes of disagreement in a sample and duplicate pair, prior to a final decision on usability of the data.	Duplicate samples are QC samples that are evaluated as part of the validation process, which includes a rigorous QC review. Lack of precision between duplicate pairs is evaluated during validation, and the results would be qualified accordingly.
17	Section 4	The document should clarify that the assessment is being developed to protect the "Reasonably Maximum Exposed" individual who is at the 90th percentile or above on the distribution of exposures consistent with EPA's 1992 Exposure Assessment Guidelines. The discussion of "measures of central tendency" should clarify that the data used in the calculation of the exposure point concentration is the 95th UCL on the mean or the maximum concentration when the dataset consists of less than 10 points.	Language has been augmented to state that the HHRA will evaluate the reasonably maximum exposed (RME) individual, who is at the 90th percentile or above on the distribution of exposures consistent with EPA's 1992's Exposure Assessment Guidelines, and the central tendency exposure (CTE) individual, who represents average exposures. The Revised RARC plan currently states "For datasets of 5 to 10 samples, as agreed with USEPA, the UCL recommended by ProUCL will be used if it is below the maximum, and these situations will be identified in the text of the risk assessment." Consistent language has been added to Section 5.
18	Section 4.1	It might be best to define when normalization is desired, and when non-normalized data are most appropriate. Each provides different information that is valuable. We suggest calculating both OC and lipid normalized BSAFs and non-normalized BSAFs. For use in food web modeling, actual tissue concentrations are preferred (for prey items). If prey tissue concentrations are to be estimated or modeled using BSAFs, then in those cases non-normalized BSAFs are often preferred.	Language has been revised stating that both normalized and non-normalized data will be considered in the development of BSAFs, and that the bioaccumulation model will evaluate non-normalized data.

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19	Section 4.2	For Equations 4-3 and 4-4, a QC step should also be performed to check that the sum of fractions is 1. In addition, there may be specific ecological exposures where these reconstituted whole-body tissue estimates may provide inaccurate exposure estimates (*e.g.*, fish bones and crab shell parts are typically not ingested by scavengers). This type of information should also be included in the uncertainty analysis.	The Data Usability and Data Evaluation Plan was revised to state that any specific issues associated with the use of reconstituted whole body concentrations will be included in the uncertainty analysis. This discussion will include any issues associated with any alternative analysis technique. It should be noted that the use of reconstituted fish for supporting the ecological risk assessments was agreed upon between CPG and USEPA in the development of the tissue compositing plans. Please note, that by definition, the sum of the fractions will equal 1, because the weight of the WB will be sum of the components.
20	Section 4.4	RAGS, Part A, Pages 8-7 and 8-8, discusses the use of significant figures. Consistent with the guidance, the final presentation of calculated risks should be provided with one significant figure.	Significant figures for calculated human health risk will be reported consistent with RAGS guidance. Consistent language has been added to Section 4.4.
21	General Comment (Page 1)	Here is some guidance for the COPC selection process memo, that you will be submitting shortly: For the human health risk assessment we compare the maximum concentration found in a specific media (i.e., soil, sediment, groundwater, air, surface water, etc.) to their respective chemical specific risk based concentration found in the Regional Risk Assessment Table. For soils or sediment we would use the residential soil values. The Regional Tables for fish consumption are available at: http://www.epa.gov/reg3hwmd/risk/human/index.htm. For carcinogens the comparison values are based on a risk of one in a million consistent with the point of departure for determining remediation goals for alternatives when ARARS are not available and are not sufficiently protective because of multiple contaminants at a site or multiple pathways of exposures (NCP Rule 40 CFR 300.430(e)(2). For systemic toxicants, we apply a Hazard Quotient (HQ) of 0.1 for noncarcinogens to account for additive effects. All known carcinogens, regardless of risk based concentrations, are maintained in the risk assessment based on RAGS, Part A. Also, consistent with the Background guidance, COPCs are not screened out based on background. Background is evaluated in the Risk Characterization consistent with the RAGS Part A and also the Background policy and guidance.	Comment noted. Please see the revised RARC Plan and COPC Selection Process Memo (Appendix A of the RARC Plan).